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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/652,814	08/29/2003	Gretchen M. Unger	0269.01/C	2748

25871 7590 09/15/2009

SWANSON & BRATSCHUN, L.L.C.
8210 SOUTHPARK TERRACE
LITTLETON, CO 80120

EXAMINER	
POPA, ILEANA	

ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
09/15/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

efspatents@sbiplaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/652,814	UNGER, GRETCHEN M.	
	Examiner	Art Unit	
	ILEANA POPA	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *66,67,87-94 and 133-141* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/15/2009; 01/13/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 66-95,97-100,102-109,111-116,118,119,122-124,126,127 and 133-141.
Continuation of Disposition of Claims: Claims withdrawn from consideration are 95,97-100,102-109,111-116,118,119,122-124,126 and 127.

DETAILED ACTION

1. In view of Panel Decision from the Pre-Appeal Brief conference held on 07/09/2009, PROSECUTION IS REOPENED and a new Office action is hereby issued.

Claims 1-65, 96, 101, 110, 117, 120, 121, 125, and 128-132 have been cancelled. Claims 68-86, 95, 97-100, 102-109, 111-116, 118, 119, 122-124, 126, and 127 have been withdrawn.

Claims 66, 67, 87-94, and 133-141 are under examination.

2. Upon further considerations, the rejection of claims 66, 67, 87, 88, 90-94, 135, and 137-139 under 35 U.S.C. 102(e) as being anticipated by Unger et al. (US Patent No. 6,139,819), as evidenced by Kondo et al. (Anal. Chem., 1991, 198: 30-35, Abstract).

Upon further considerations, the following rejections are withdrawn in favor of new and revised rejections:

The rejection of claims 66, 67, 87, 88-94, 133-135, and 137-141 under 35 U.S.C. 103(a) as being unpatentable over Unger et al. taken with Kondo et al., in view of Schneider et al. (FEBS Letters, 1998, 429: 269-273);

The rejection of claims 66, 67, 87, 88, 90-94, and 135-139 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Unger et al. taken with Kondo et al., in view of each Medina (U.S. Patent No. 5,650,543), Quay (U.S. patent No. 5,707,606), and Duquemin et al. (J Pharm Pharmacol, 1985, 37: 698-702, Abstract).

Specification

3. The use of the trademarks Qiaquik, Zymoclean, Synergel, SybrGold, and Storm 860 has been noted in this application (p. 23, lines 20-25). It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 67, 87, 88, 90, 94, 133, 134, and 136-141 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8 and 11 of copending Application No. 12/027,863. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are obvious variants.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is noted that the instant rejection has not been previously presented because Application No. 12/027,863 was filed on 02/07/2008, which is after the mailing date of the non-final Office action of 12/11/2007. It is also noted that Application No. 12/027,863 is a continuation of Application No. 10/958,999 and that claims 8 and 11 of Application No. 12/027,863 are identical to claims 10 and 13 of the abandoned Application No. 10/958,999. Therefore, the instant rejection is the same as the obviousness-type double patenting rejection previously made over claims 10 and 13 of Application No. 10/958,999 (see the non-final Office action of 12/11/2007).

The instant claims are drawn to a composition of nanocapsules comprising (i) a surfactant micelle consisting of a bioactive component that has a therapeutic effect and a surfactant having an HLB value of less than about 6.0, and (ii) a shell surrounding the surfactant micelle, wherein the shell comprises a precipitate containing a polypeptide and a cationic precipitating agent and wherein the polypeptide provides specific cellular by binding to cell surface antigens or receptors; the particles have an average diameter of less than 50 nm as measured by atomic force microscopy after drying of the particles

(claims 66 and 139). The cation can be Li^+ (claims 94, 138, and 139), the polypeptide comprises tenascin (claims 133, 134, 140, and 141), the bioactive component is a polynucleotide (claims 67 and 139), which can be associated with a nucleic acid condensing agent (claim 137), the surfactant has a HLB of less than 5.0 (claim 88) and can be a non-ionic (claim 87) or is selected from the group recited in claims 90 and 136. The specification defines that the polynucleotide could be an anti-sense DNA (p. 23, line 1).

The application claims recite a collection of particles comprising an agent, a surfactant molecule having an HLB of less than 6.0, a polymer soluble in aqueous solution, wherein the collection of particles has an average diameter of less than about 100 nm as measured by atomic force microscopy after drying and wherein the agent is an anti-sense nucleic acid (claim 8). The collection of particles further comprises a cell recognition agent (claim 11). The specification defines that the surfactant can be a non-ionic surfactant or 2,4,7,9-tetramethyl-5-decyn-4,7-diol, as recited in the instant claims 87, 88, 90, and 136 (i.e., a surfactant with an HLB of less that 5.0), the particles further comprise Li^+, wherein Li^+ is used to precipitate the biocompatible polymer that surrounds the micelles comprising the surfactant and bioactive agent, and the polymer can be tenascin (p. 8, lines 8 and 9, p. 12, lines 8-23, p. 17-18, Table 1, p. 56, lines 5 and 6). With respect to the limitation of nanocapsule, the specification defines that the particles can be formulated as nanocapsules (p. 13, lines 8 and 9). With respect to the limitation of the polynucleotide being associated with a nucleic acid condensing agent,

one of skill in the art would know to do this because the art teaches that condensing are always used when delivering nucleic acids via nanoparticles.

Thus, the application claims and the instant claims are obvious variants of one another.

6. Claims 66, 67, 87, 88, 90, 94, 133, 134, and 136-141 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 25-28 of copending Application No. 11/622,359. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are obvious variants.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The instant claims are drawn to a composition of nanocapsules comprising (i) a surfactant micelle consisting of a bioactive component that has a therapeutic effect and a surfactant having an HLB value of less than about 6.0, and (ii) a shell surrounding the surfactant micelle, wherein the shell comprises a precipitate containing a polypeptide and a cationic precipitating agent and wherein the polypeptide provides specific cellular by binding to cell surface antigens or receptors; the particles have an average diameter of less than 50 nm as measured by atomic force microscopy after drying of the particles (claims 66 and 139). The cation can be Li^+ (claims 94, 138, and 139), the polypeptide comprises tenascin (claims 133, 134, 140, and 141), the bioactive component is a polynucleotide (claims 67 and 139) which can be associated with a nucleic acid

condensing agent (claim 137), the surfactant has a HLB of less than 5.0 (claim 88) and can be a non-ionic (claim 87) or is selected from the group recited in claims 90 and 136.

The application claims drawn a collection of particles having a bioactive component, a surfactant with an HLB less than 6.0, a biocompatible polymer, and a cell recognition component having affinity for a cell receptor; the average diameter of the particles is less than 50 nm as measured by atomic force microscopy after drying of the particles (claim 25), wherein the bioactive component is a polynucleic acid (claim 28) and wherein the biocompatible polymer is tenascin claims 26 and 27). The specification defines that: **(i)** the surfactant can be a non-ionic surfactant or 2,4,7,9-tetramethyl-5-decyn-4,7-diol (i.e., a surfactant that has an HLB of less than 5.0, as recited in the instant claims 87, 88, 90, and 136), **(ii)** the particles comprise surfactant micelles containing surfactant and a bioactive agent, **(iii)** the biocompatible polymer forms a shell surrounding the surfactant micelles, and **(iv)** the biocompatible polymer is precipitated by cations such as Li^+ (p. 9. lines 21-23. p. 10, lines 1-21, p. 75, lines 15-18, p. 76, lines 3-13). With respect to the limitation of nanocapsule, the specification disclosed that the particles can be formulated as nanocapsules (p. 11, lines 6 and 7). With respect to the limitation of the polynucleotide being associated with a nucleic acid condensing agent, this is not innovative over the prior art, which teaches that condensing agents are always used when delivering nucleic acids via nanoparticles.

Thus, the application claims and the instant claims are obvious variants of one another.

7. Claims 66, 67, 87, 88, 90, 93, 94, 133, 134, and 136-141 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 29, 31, 33, 37, and 42 of U.S. Patent No. 6,632,671.

The instant claims are drawn to a composition of nanocapsules comprising (i) a surfactant micelle consisting of a bioactive component that has a therapeutic effect and a surfactant having an HLB value of less than about 6.0, and (ii) a shell surrounding the surfactant micelle, wherein the shell comprises a precipitate containing a polypeptide and a cationic precipitating agent and wherein the polypeptide provides specific cellular by binding to cell surface antigens or receptors; the particles have an average diameter of less than 50 nm as measured by atomic force microscopy after drying of the particles (claims 66 and 139). The cation can be Li^+ (claims 94, 138, and 139), the polypeptide comprises tenascin (claims 133, 134, 140, and 141), the bioactive component is a polynucleotide (claims 67 and 139) which can be associated with a nucleic acid condensing agent (claim 137), the surfactant has a HLB of less than 5.0 (claim 88), the surfactant can be non-ionic (claim 87) or is selected from the group recited in claims 90 and 136, the composition further comprises a water-miscible solvent (claim 93).

The patent claims recite a plurality of particles comprising a surfactant with an HLB less than 5.0, a bioactive hydrophobic component (i.e., a bioactive component), and a biocompatible polymer, wherein the particles have an average diameter of less than 50 nm as determined by atomic force microscopy and wherein the biocompatible polymer is precipitated in the presence of a cation (claims 29, 37, and 42). The surfactant can be a non-ionic surfactant or 2,4,7,9-tetramethyl-5-decyn-4,7-diol (claim

33), as recited in the instant claims 87, 90, and 136, and the particles further comprise a water-miscible solvent (claim 31). With respect to the limitation of the biocompatible polymer providing specific cellular uptake, the specification discloses that the biocompatible polymer can be tenascin (see fig. 7B, and also column 3, lines 6-8). The specification discloses that the biocompatible polymer forms a shell surrounding the surfactant micelles containing the bioactive component and the surfactant, the hydrophobic bioactive component can be a polynucleic acid, and that the precipitating cation is Li^+ (Abstract, column 3, lines 25-32, column 5, lines 37-59, column 7, lines 32-37, column 9, lines 40-45, column 10, lines 42-66, column 15, lines 30-32). With respect to the limitation of HLB being less than 6.0, the patent claims recite an HLB less than 5.0 that anticipates the claimed HLB of less than 6.0. With respect to the limitation of nanocapsules, the specification discloses that the particles are formulated as nanocapsules (Abstract). With respect to the limitation of the polynucleotide being associated with a nucleic acid condensing agent, this is not innovative over the prior art, which teaches that condensing are always used when delivering nucleic acids via nanoparticles.

Therefore, the patent claims and the instant claims are obvious variants of one another.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 66, 67, 87-94, and 135-139 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger et al. (US Patent No. 6,139,819, of record), in view of each Kondo et al., in view of each Medina (U.S. Patent No. 5,650,543, of record), Quay (U.S. Patent No. 5,707,606, of record), and Duquemin et al. (J Pharm Pharmacol, 1985, 37: 698-702, Abstract, of record).

Unger et al. teach particles comprising a core provided by monomolecular layers of surfactant micelles consisting of a non-ionic surfactant and a bioactive agent which has a therapeutic effect, wherein the surfactant micelles are stabilized by a surrounding protein shell; the protein shell is covalently coupled with targeting ligands that bind cell surface receptors (i.e., the protein provides specific cellular uptake), wherein the covalent coupling involves the formation of Schiff base linkages which are reduced by using lithium aluminum hydride (claims 66, 87, 94, 135, 138, and 139) (column 6, lines 52-61, column 8, lines 1-3 and 44-47, column 14, lines 10-12, column 15, lines 62-65, column 16, lines 18-26, column 17, line 60, column 18, line 61, column 30, lines 18-32 , 66, and 67, column 31, lines 29 and 30, column 34, lines 24-49, column 38, lines 13-17,

column 48, lines 43-45, column 49, lines 1-8, column 59, lines 66 and 67, column 60, lines 1-4 and 16-24). Unger et al. teach that the bioactive agent could be a polynucleic acid which is associated with cationic lipids (i.e., a condensing agent) (claims 67 and 137) (column 9, lines 36-50, column 10, lines 13-23, column 60, lines 16-21). Unger et al. teach their particles as having a hollow core comprising the bioactive agent (column 60, lines 1-4 and 16-24), i.e. they teach nanocapsules (see also Applicant's definition of nanocapsules, on p. 5, lines 21-24 of the instant specification). Unger et al. also teach that the particles have a size of about 30 nm (claims 66 and 139) (column 28, lines 51-53), that the particles can comprise a combination of two or more surfactants (claim 91) (column 19, lines 21-25, column 31, lines 52-57), a biocompatible oil, such as peanut oil (claim 92) (column 33, lines 23-25), and a water-miscible solvent (claim 93) (Example 4). With respect to the limitation of the protein shell being precipitated by the cation, wherein the cation is Li^+ (claims 66 and 139), this is inherent to the nanocapsules of Unger et al., since the covalent attachment of the targeting ligand requires addition of lithium aluminum hydride (see above), which would necessarily result in a precipitated protein shell (it is noted that Li^+ is known in the art as a protein precipitating agent, see for example Kondo et al., Abstract).

Unger et al. do not specifically teach that the surfactant is an acetylenic diol such as 2,4,7,9-tetramethyl-5-decyne-4,7-diol, i.e., surfactants with an HLB less than about 5.0 (claims 66, 88, 90, 136, and 139). However, using such is suggested by the prior art. For example, Medina teaches the acetylenic diol 2,4,7,9-tetramethyl-5-decyne-4,7-diol and its ethoxylates as excellent surfactants because of their ability to decrease the

surface tension (Abstract, column 1, lines 30-35, column 3, lines 3-5). Quay teaches the use of acetylenic diols or blends thereof for the preparation of stable and biocompatible nanoparticles, wherein acetylenic diols stabilize the nanoparticles by lowering the surface tension (column 3, lines 15-20, column 7, lines 9-16). Duquemin et al. teach that reducing the surface tension results in smaller particles (Abstract). Based on these teachings in the prior art, one of skill in the art would have known that acetylenic diols (such as 2,4,7,9-tetramethyl-5-decyne-4,7-diol) could be used to obtain small and stable the size of biocompatible nanoparticles suitable for efficient gene delivery. Therefore, it would have been obvious to one of skill in the art, at the time the invention was made, to modify the particles of Unger et al. by using 2,4,7,9-tetramethyl-5-decyne-4,7-diol, with a reasonable expectation of success. One of skill in the art would have been motivated to do so because the prior art teaches that the use of acetylenic diols such as 2,4,7,9-tetramethyl-5-decyne-4,7-diol results in nanoparticles with improved properties. One of skill in the art would have been expected to have a reasonable expectation of success in making such a composition because the art teaches that acetylenic diols can be successfully used in the preparation of nanoparticles for the *in vivo* delivery of agents. With respect to the limitation of the surfactant having a critical micelle concentration of about 200 μm (claim 89), absent evidence of unexpected results, it would have been obvious to one of skill in the art to vary the parameters in a given method with the purpose of optimizing the results, i.e., to use a surfactant with the desired critical micelle concentration according to the intended use of the particles. Again, absent evidence to the contrary, it is generally not inventive

to discover the optimal working conditions of a prior art method, such conditions can be identified by routine experimentation.

Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

10. Claims 66, 67, 87-94, and 133-141 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger et al. taken with each Kondo et al., Medina, Quay, and Duquemin et al., in further view of Schneider et al. (FEBS Letters, 1998, 429: 269-273).

The teachings of Unger et al., Kondo et al., Medina, Quay, and Duquemin et al. are applied as above for claims 66, 67, 87-94, and 135-139.

Unger et al., Kondo et al., Medina, Quay, and Duquemin et al. do not teach tenascin (claims 133, 134, 140, and 141). Schneider et al. teach identification of a polypeptide derived from the C-terminus of tenascin (claims 133 and 140) capable to bind to $\alpha_9\beta_1$ integrins on the cell surface, i.e., Schneider et al. also teach a ligand that targets a receptor for tenascin (claims 134 and 141) (Abstract, p. 272, column 2 first paragraph and Fig. 4). Schneider et al. also teach their peptide as being suitable to mediate specific gene delivery to $\alpha_9\beta_1$ integrin-expressing cells (Abstract, p. 269, column 2, second paragraph, p. 272, column 2, second and third paragraphs). It would have been obvious to one of skill in the art, at the time the invention was made to modify the nanocapsules of Unger et al., Kondo et al., Medina, Quay, and Duquemin et al. by replacing their targeting ligands with the peptide of Schneider et al. with the intent to target the particles to $\alpha_9\beta_1$ integrin-expressing cells, with a reasonable expectation of

success. The motivation to do so is provided by Schneider et al., who teach that targeting $\alpha_9\beta_1$ integrin is promising for the development of gene therapy delivery vehicles since $\alpha_9\beta_1$ integrin is highly expressed on human airway epithelia irrespective of any clinical status (p. 269, column 1 bridging column 2). One of ordinary skill in the art would have been expected to have a reasonable expectation of success in making such particles because Unger et al. teach that peptide ligands can be successfully included in their nanocapsules.

Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

11. No claim is allowed. No claim is free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILEANA POPA whose telephone number is (571)272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ileana Popa/
Primary Examiner, Art Unit 1633